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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,047	12/07/2000	Edwin F. Ullman	BEH-7385	9672

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DADE BEHRING INC.
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EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/732,047

Applicant(s)

ULLMAN ET AL.

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 20, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges Applicants' reply, filed November 20, 2006. Claim 44 is amended. Currently, claims 44-46 are pending and under examination.

Specification

The amendment filed December 2, 2005, is further objected to because of the following informalities:

Amendment to the paragraph on page 5, lines 1-14:

The mechanism by which "release of the substrate with formation of a first binding site may be accompanied by unmasking of at least some of a second binding site" is mechanistically unclear.

The amendment filed March 31, 2006, is objected to because of the following informalities:

Amendment to the paragraph on page 9, lines 5-22:

The sentence "When peroxide or singlet oxygen is generated, an oxidant cleavable linker is cleaved, releasing ~~the multiple substrates as~~ multiple products" (emphasis as amended) is indefinite. How cleaving a linker results in release of "multiple products" is not clear.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 44, the term "water-insoluble" is indefinite. The identity of one or more standards or conditions for ascertaining solubility is not clear and appears omitted from Applicants' specification. Whether claim 44 requires "water" is not clear.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bronstein *et al.* (US 6,243,980) in view of Pease *et al.* (US 5,709,994).

Bronstein *et al.* describe a method for determining the presence or concentration of an analyte in a medium, said method comprising:

(1) providing a reacting mixture comprising in combination:

(a) a medium (see Abstract, first sentence, "sample") suspected of containing an analyte (see Title, "protease inhibitor"; see *also* col. 7, lines 13-14, "the other member of the first pair");

(b) a first specific binding pair member (see Fig. 3, "alkaline phosphatase") bound to a solid support (see Fig. 3, adamantyl moiety);

(c) a second specific binding pair member (see Fig. 3, OPO_3^-) bound to a sensitizer (see col. 5, line 35, "1,2-dioxetane moiety precursor") capable in its excited state of generating a reactive oxygen species (see col. 5, lines 36-37, "photooxygenated in situ to the dioxetane (14B)"), wherein the proximity of the first specific binding pair member with the

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second specific binding pair member is modulated by the presence of the analyte (see Abstract, fifth and sixth sentences, "Substrate cleavage, if not inhibited, is allowed to occur, and any unbound cleaved fragments are removed. An enzyme complexed with the second member of the second ligand binding pair is added, and allowed to bind to any of the (uncleaved) first member of the second ligand binding pair remaining");

(d) digoxigenin-linked biotin (see col. 7, lines 10-12, "labels for either end of the peptide are: Biotin... and Digoxin (digoxigenin labeled peptide)") (paraphrasing mine) linked to the support (see Fig. 3, adamantyl moiety) through a reactive oxygen cleavable linker (see Abstract, first sentence, "1,2-dioxetanes");

(2) incubating the reaction mixture (see Abstract, fifth sentence, "Substrate cleavage, if not inhibited, is allowed to occur");

(3) exciting the sensitizer, said excitation of the sensitizer causing the formation of reactive oxygen, which cleaves the cleavable linker and releases digoxigenin-linked biotin from the support (see Fig. 3 and col. 3, lines 6-7, "decomposition"); and

(4) detecting the released digoxigenin-linked biotin, the amount thereof being related to the amount of analyte in said medium (see Abstract, last sentence, "when the dioxetane is caused to decompose, energy is transferred to the fluorescing entity, which releases light of a wavelength recognizably distinct").

Bronstein *et al.* do not describe "water-insoluble" solid supports.

However, Pease *et al.* describe "water-insoluble" solid supports (see Title, "matrices") for general use in chemiluminescence assays (see Abstract, fifth sentence).

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It would have been obvious for a person of ordinary skill to perform the analyte determination of Bronstein *et al.* with "water-insoluble" solid supports because Pease *et al.* discovered "water-insoluble" solid supports that allow separation of bound binding partners from unbound binding partners (see col. 10, lines 8-12). Furthermore, Pease *et al.* discovered "water-insoluble" solid supports with "delayed luminescence" lifetimes, which can be modulated as a function of structure and/or composition (see col. 8, lines 1-9).

Response to Arguments

Specification

In prior Office Action, Examiner objected to the amendment filed December 2, 2005, specifically, the amendment to the paragraph on page 5, lines 1-14, because the mechanism by which "release of the substrate with formation of a first binding site may be accompanied by unmasking of at least some of a second binding site" (emphasis mine) is considered mechanistically unclear.

In response, Applicants point to allegedly analogous mechanisms of:

- (1) a substrate linked to a support via a linker, whereupon cleavage of the linker unmask a binding site (see Applicants' reply, paragraph bridging pp. 6-7, second sentence; see also, p. 8, last paragraph);
- (2) supports having "pores" (see Applicants' reply, paragraph bridging pp. 6-7, fifth sentence);
- (3) specific binding reagents that are "bulky" (see Applicants' reply, paragraph bridging pp. 6-7, sixth sentence); and
- (4) unmasking of biotin (see Applicants' reply, p. 7, bottom paragraph, to p. 8, second paragraph, "the free amino group on the biotin represents the formation of the first binding site and the unmasked biotin represents unmasking of the second binding site").

Applicants' arguments are not persuasive. None of (1) to (3) are analogous to the mechanism as described in the amendment filed December 2, 2005. None of (1) to (3) describe a mechanism involving both: (a) formation of a first binding site; and (b) unmasking of a second binding site.

Applicants' specification has no support for either assignment of "binding site" set forth in (4).

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Claim Rejections - 35 USC § 102

In prior Office Action, claims 44-46 were rejected under 35 U.S.C. 102(e) as being anticipated by Bronstein *et al.* (US 6,243,980).

In response, Applicants amend independent claim 44 to add reference to "water-insoluble" supports. Notwithstanding issues of indefiniteness, set forth *supra*, *Claim Rejections - 35 USC § 112*, Applicants' amendment appears sufficient to overcome this rejection. Accordingly, this rejection is withdrawn.

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Conclusion

No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Oh & Kearns (US 5,534,620) are cited for their description of digoxigenin-linked biotin (see col. 17, lines 46-67) for probing hormone-linked receptors (see col. 14, lines 13), relevant to claims 44-46.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

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